

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
 v.)
)
AMERICAN HOME PRODUCTS)
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8950

Bartle, J.

October 24, 2012

Elliot J. Palay ("Mr. Palay" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2003, claimant submitted a completed supplemental Green Form to the Trust signed by his attesting physician, Raye L. Bellinger, M.D., F.A.C.C., F.S.G.C. Based on an echocardiogram dated November 10, 1998, Dr. Bellinger attested in Part II of Mr. Palay's supplemental Green Form that claimant suffered from New York Heart Association Functional Class III symptoms and a left ventricular ejection fraction < 40% at any time six months or later after valvular repair or replacement surgery.³ In addition, Dr. Bellinger attested that Mr. Palay had

2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who has factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Bellinger also attested that claimant suffered from
(continued...)

surgery to repair or replace the aortic and/or mitral valve after use of Pondimin® and/or Redux™. Based on such findings, claimant would be entitled to Matrix A-1, Level V⁴ benefits.⁵

Claimant submitted echocardiogram reports dated November 10, 1998 and January 18, 2001. In the report of claimant's November 10, 1998 echocardiogram, the reviewing cardiologist, David S. Rubenson, M.D., stated that claimant's "left ventricular ejection fraction is markedly reduced (25-35%)." In the report of claimant's January 18, 2001 echocardiogram, the reviewing cardiologist, Merri McMahon, M.D.,

3. (...continued)

severe mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left ventricular end-systolic dimension, an abnormal left atrial dimension, arrhythmias, and a reduced ejection fraction in the range of 30% to 34%. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for payment at Matrix Levels III or IV and has New York Heart Association Functional Class III or Class IV symptoms, underwent surgery to repair or replace the aortic and/or mitral valve(s), and had a left ventricular ejection fraction of less than 40% six months or later after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b)(ii). As the Trust does not contest that claimant qualifies for payment at Matrix Level III and had valvular repair or replacement surgery, the only issues are whether claimant suffers from New York Heart Association Functional Class III symptoms and had an ejection fraction of less than 40% six months or more after his valvular repair or replacement surgery.

5. Mr. Palay previously was paid Matrix B-1, Level IV benefits. Thus, if Mr. Palay's supplemental claim for Matrix A-1, Level V benefits is payable, he only will receive the amount in addition to the previous payment he received. See Settlement Agreement § IV.C.3.

noted that claimant's ejection fraction was 40.9%. An ejection fraction is considered reduced for a Level V Matrix claim if it is measured as less than 40% six months or more after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b)(ii)(d).

In or around April, 2004, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. Bellinger's finding that claimant suffered from New York Heart Association Functional Class III symptoms because "[t]here is no documentation as to patient status at the time of the green form." In addition, Dr. Oliner determined that claimant's November 10, 1998 echocardiogram demonstrated that his "ejection fraction is approximately 40%."⁶

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Mr. Palay's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this

6. Dr. Oliner also concluded that claimant suffered from "acute inferior wall myocardial infarction accompanied by acute mitral regurgitation," the presence of which reduces a claim to Matrix B. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c). Given our disposition, we do not need to reach this argument. We note, however, that the Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., reviewed claimant's medical records and determined that they "demonstrated classic findings for acute mitral regurgitation secondary to an acute inferior myocardial infarction."

adverse determination.⁷ In contest, claimant argued that Dr. Oliner either was not supplied with or did not review the October, 2003 supplemental Green Form and additional materials that claimant contended were part of the record, including the April 5, 2002 supplemental Green Form completed by Dr. Rubenson, the March 6, 2001 and April 5, 2002 supplemental Green Forms completed by Giacomo DeLaria, M.D., and the operative report of Mr. Palay's November 11, 1998 surgery. Finally, claimant contends that there is sufficient proof that he meets the requirements of a Level V Matrix claim and that his claim should be approved.⁸

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). As this claim was placed into audit on April, 2004, the Audit Rules contained in PTO No. 2807 apply to Mr. Palay's claim.

8. Claimant also raises a number of arguments related to the presence or absence of several reduction factors the Trust identified during audit. Given our disposition, we need not address these additional arguments. In addition, claimant argues that he was 49, not 52, years of age when he was first diagnosed with a reduced ejection fraction and that the Trust is in possession of a "missing audit" because he received "Verification Notices," which, according to Mr. Palay, only are sent to claimant's potentially payable on Matrix A. We previously rejected both of these contentions. In PTO No. 5575 (Aug. 16, 2005), we determined that 52 is the correct age of diagnosis, id. at 13-14, and that there is no evidence of a "missing audit," id. at 4-6.

Dr. Oliner submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's findings that Mr. Palay suffered from New York Heart Association Functional Class III symptoms or had a left ventricular ejection fraction < 40% six months or later after valvular repair or replacement surgery. Specifically, Dr. Oliner stated, in relevant part, that:

9. In accordance with the Trust's request, I again reviewed the claim, including Claimant's echocardiogram tapes and supplemental Green Form, as well as Claimant's Contest materials, including the referenced exhibits.

In connection with my review, I evaluated the chest X-ray reports and EKG that Claimant submitted in support of his contention that he has New York Heart Association Functional Class III symptoms. The EKG depicts Claimant in sinus rhythm with premature ventricular contractions, and not in atrial fibrillation, as Claimant asserts.

I also found that the chest X-ray reports do not document that Claimant has Class III symptoms. I again concluded that Claimant has provided no documentation of New York Heart Association Functional Class III symptoms.

10. I again evaluated Claimant's ejection fraction on his post-surgery echo, dated January 18, 2001. I found that Claimant's ejection fraction as depicted in this study is clearly no less than 45% and, indeed, is likely 45%-50%.

The Trust also responded that it was not in possession of a "missing audit." According to the Trust, at the time Mr. Palay submitted his DDR Acknowledgment and Physician Verification, it was the Trust's practice to begin Court Approved Procedure No. 4

compliance (i.e., sending verification notices) prior to completion of medical review.

The Trust then issued a final post-audit determination again denying Mr. Palay's supplemental claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement.⁹

See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Palay's claims should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5245 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 11, 2006, and claimant submitted a sur-reply on August 28, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust

9. Claimant also filed an Appeal to District Court from Trustees' and/or Claims Administrator's Determination of Benefits ("Appeal") regarding the Trust's determination of the duration of claimant's Diet Drug use. Given our disposition, it is not necessary to resolve this issue. Accordingly, we will dismiss claimant's Appeal as moot.

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 (continued...)

and claimant have had the opportunity to develop the show cause record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Dr. Vigilante, to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id.

Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that he suffered from New York Heart Association Functional Class III symptoms as documented by an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist and was diagnosed with a left ventricular ejection fraction < 40% six months or more after valvular repair or replacement surgery. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's supplemental Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order

10. (...continued)

F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Palay argues that there is a reasonable medical basis for the attesting physician's supplemental Green Form representation that he suffers from New York Heart Association Functional Class III symptoms because Dr. Bellinger attested that Mr. Palay suffered from the required excessive fatigue and dyspnea. According to claimant, Dr. Bellinger submitted an EKG dated September 27, 2003 that "clearly demonstrates that Mr. Palay has chronic atrial fibrillation/flutter." (Emphasis in original.) In addition, Mr. Palay contends that he suffers from congestive heart failure, pulmonary edema, and pulmonary vascular congestion, each of which is a New York Heart Association Functional Class III symptom. Mr. Palay also argues that the Trust should not be allowed to question the level of his ejection fraction six months after surgery because the Trust already determined he was entitled to payment of Level IV Matrix Benefits, which was based, in part, on a Green Form representation that he suffered from a left ventricular ejection fraction of < 40% six months after valvular repair or replacement surgery.

In response, the Trust argues that Mr. Palay has failed to establish that he suffered from New York Heart Association Class III symptoms because his EKG dated September 27, 2003 does not show atrial fibrillation. The Trust also contends that Dr. Bellinger's finding of a left ventricular ejection fraction

< 40% six months after valvular repair or replacement surgery is incorrect because Dr. Oliner determined claimant's ejection fraction was between 45% and 50% and the report of claimant's echocardiogram lists his ejection fraction as 40.93% by Teicholz method and 49.42% by the cubed method. Finally, the Trust asserts that it is not barred from raising the issue of claimant's ejection fraction because Mr. Palay's original claim was not subjected to the current 100%¹¹ audit requirement.¹²

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's findings that claimant suffered from New York Heart Association Functional Class III symptoms as documented by an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist or a left ventricular ejection fraction < 40% six months or later after valvular repair or replacement surgery. In particular, Dr. Vigilante determined that:

... [T]here is not a reasonable medical basis for the Attesting Physician's answer to Green Form Question G. The classification of Claimant's New York Heart Association Functional Class is based on his symptoms during his visit to a health professional. There were no medical records around the time frame of October 24, 2003 which indicated

11. In PTO No. 2662 (Nov. 26, 2002), we mandated a 100% audit requirement for all claims for Matrix Benefits.

12. In his sur-reply, claimant responds only to the Trust's determination that he suffers from acute myocardial infarction associated with acute mitral regurgitation, which we do not address here.

Mr. Palay's cardiac symptoms. There was no documentation by Dr. Bellinger that he interviewed and examined the Claimant at the time he signed the Green Form on October 24, 2003....

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question K. That is, the echocardiogram of January 18, 2001 demonstrated a left ventricular ejection fraction of 44%. This ejection fraction did not come close to being less than 40%. An echocardiographer could not reasonably conclude that an ejection fraction of less than 40% was present on the study of January 18, 2001 even taking into account inter-reader variability.¹³

After reviewing the entire Show Cause Record, we find that claimant has failed to establish a reasonable medical basis for his claim. Dr. Oliner reviewed Mr. Palay's medical records and found that "Claimant has provided no documentation of New York Heart Association Functional Class III symptoms." He explained, "The EKG depicts Claimant in sinus rhythm with premature ventricular contractions, and not in atrial fibrillation, as Claimant asserts." Dr. Vigilante also reviewed claimant's medical records and similarly concluded that "there is no documentation that the Claimant had Class III symptoms at the time that the Supplemental Green Form was completed." Despite an opportunity to do so, Mr. Palay did not respond to this portion of Dr. Vigilante's Technical Advisor Report. Thus, claimant has not demonstrated a reasonable medical basis for the attesting

13. In his response to the Technical Advisor Report, claimant responds only to Dr. Vigilante's determination that claimant suffers from acute myocardial infarction associated with acute mitral regurgitation, which we do not address here.

physician's representation that Mr. Palay suffered from New York Heart Association Functional Class III or Class IV symptoms as documented by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist.

Claimant also has failed to meet his burden with respect to proving a reasonable medical basis for the attesting physician's supplemental Green Form representation that he had an ejection fraction of less than 40% six months or more after valvular repair or replacement surgery. As an initial matter, the report of claimant's echocardiogram lists Mr. Palay's ejection fraction as 40.93% by Teicholz method and 49.42% by the cubed method. In addition, Dr. Oliner reviewed claimant's January 18, 2001 echocardiogram and found that "Claimant's ejection fraction six months after his valve surgery was approximately 45%-50%." Dr. Vigilante confirmed the auditing cardiologist's finding, noting that "the echocardiogram of January 18, 2001 demonstrated a left ventricular ejection fraction of 44%."¹⁴ Despite submitting a response to the Technical Advisor Report, claimant did not challenge Dr. Vigilante's finding in this regard. In particular, claimant failed to address the Technical Advisor's specific conclusion

14. We reject claimant's argument that the Trust should not be allowed to challenge the finding with regard to his ejection fraction because the Trust already determined he was entitled to payment of Level IV Matrix Benefits. Each claim for benefits is separate and subject to audit. In addition, the Trust did not audit the level of Mr. Palay's ejection fraction in connection with his initial claim, which was filed before the 100% audit requirement was imposed.

that his "ejection fraction did not come close to being less than 40%." Claimant, therefore, has failed to meet his burden of demonstrating that there is a reasonable medical basis for his claim.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for his claim for Matrix A-1, Level V benefits. Therefore, we will affirm the Trust's denial of Mr. Palay's claim for Level V Matrix Benefits.¹⁵

15. We will deny as moot the motion by Wyeth for leave to participate in and limit the scope of this show cause proceeding.